DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Redacted by L. Dries 4/19/99

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
99-DT-07

April 5, 1999

Mr. Gary Wood, Administrator
Diagnostic Imaging
Providence Hospital Breast Health & Education Center
22250 Providence Dr.
Southfield, MI 48075

Dear Mr. Wood:

Your facility was inspected on March 30, 1999 by a representative of the State of Michigan, acting in behalf of the Food and Drug Administration (FDA). The inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. Your radiologic technologist, [redacted] is not qualified to conduct mammography exams in that she was not certified by an FDA recognized body, such as the ARRT, to signify competency to perform radiologic procedures. Such certification is required in addition to specific training in conducting mammography procedures equivalent to 40 contact hours.

The specific deficiency noted above appears under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. The deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition to the above violation, the following item was listed under the Level 2 heading of the MQSA Facility Inspection report:

1. The darkroom fog density was measured to be [redacted] Optical Density units (O.D.) for the mammography darkroom. The Quality Standards require that the darkroom fog not exceed 0.05 O.D. units.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action (s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify the FDA in writing of:

- the specific steps you have taken to correct the Level 1 and 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- a current test film demonstrating compliance with the maximum fog limit of 0.05 O.D. units.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to Mr. David M. Kaszubski, Compliance Officer, U.S. Food & Drug Administration,, 1560 East Jefferson Ave., Detroit, MI 48207. Also, send a copy to Mr. James Camburn, Chief, Michigan Dept. Of Consumer & Industry Services, Radiation Safety Section, P.O. Box 30664, Lansing, MI 48909. You may choose to address both FDA and State requirements in your response.

I have enclosed a copy of the MQSA Facility Inspection Report that was previously provided to your facility by the State of Michigan representative.

If you have any questions regarding this letter or how to ensure that you are meeting the MQSA Standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

for David M. Kazalski

Raymond V. Mlecko
District Director
Detroit District Office

Enclosures: a/s